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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,285	03/02/2005	Nitin Bhalachandra Dharmadhikari	006420.00004	4683

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EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,285	DHARMADHIKARI ET AL.	
	Examiner	Art Unit	
	Frederick Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-18,23 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,3-18,23 and 27* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Previous Rejections

Unless specifically repeated/maintained infra, all previous rejections are withdrawn.

Written Description Rejection (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-18 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support is seen for the limitation "described in New Drug Application No. 13-217" in claim 1 (penultimate line). Given that this is apparently a synonym for the proprietary product "Skelaxin®", it will be necessary for applicant to amend the instant specification to adequately describe the subject matter set forth in "New Drug Application No. 13-217" in generic terms. In doing so, applicant should bear in mind that incorporation of essential material in the specification by reference to a publication is improper. Applicant will thus be required to amend the disclosure to include the material incorporated by reference, since the material is being relied upon to overcome a rejection imposed by the Office. The amendment will have to be

accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. See 37 CFR 1.57(f).

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8, last line, the modifying function of the phrase "has enhanced oral bioavailability" is unclear given that same is already recited in claim 1.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1, 3-5, 7-18, 23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liversidge et al (USP 5,145,684) in view of Scaife et al (USP 6,407,128).

The primary reference discloses methods for increasing the solubility and bioavailability of hydrophobic drugs (column 1, lines 12-27) by formulating them in nanoparticulate (at least 90 percent particles of 400 nm diameter or less: see column 5, lines 20-40) crystalline form with a surface modifier, e.g., a surfactant such a sodium lauryl sulfate. See column 5, line 4. The technique is generally applicable to a wide variety of active agents (column 3, lines 38-40) expected to benefit from increased solubility and bioavailability. The prior art differs from the instant claims insofar as metaxalone is not specifically disclosed.

Metaxalone is a hydrophobic drug which would be expected to benefit from increased solubility and bioavailability. See the secondary reference at column 1, lines 57-64. Accordingly, it would have been obvious to used it as a drug substance in the primary reference methods to that end. Determination of proper dosages and adjuvant therapies to help relieve pain (such as administration of known analgesics, e.g. NSAIDS) would have been self-evident given the guidance of the secondary reference regarding treatment parameters specific to metaxalone (see column 2, lines 43-49, and column 2, lines 23-25, for instance). Furthermore, the determination of workable and/or optimal particle sizes, size distributions and surface areas as claimed would have been reasonably expected to have required the application of no more than routine experimentation on the part of the skilled artisan, consistent with established precedent. See, e.g., See In re Aller, 105 USPQ 233, 235 (CCPA 1955); In re Boesch, 205 USPQ 215 (CCPA 1980); and In re Peterson, 65 USPQ2d 1379 (Fed. Cir. 2003). (Collectively holding that it is generally prima facie obvious to determine workable or optimal values within a prior art disclosure through the application of routine experimentation).

2) Claims 1, 4-7, 15-18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al (USP 4,344,934) in view of Scaife et al (USP 6,407,128).

The primary reference discloses methods for increasing the solubility and bioavailability of hydrophobic drugs by formulating them as coprecipitates (column 5, lines 44-53) with water soluble polymers/wetting agents, e.g., surfactants such as sodium lauryl sulfate. See column 3, line 31; see also column 5, lines 20-25. The drugs may be in either amorphous or crystalline forms (column 6, first paragraph). The prior art differs from the instant claims insofar as metaxalone is not specifically disclosed.

Metaxalone is a hydrophobic drug which would be expected to benefit from increased solubility and bioavailability. See the secondary reference at column 1, lines 57-64. Accordingly, it would have been obvious to used it as a drug substance in the primary reference methods to that end. Determination of proper dosages and adjuvant therapies to help relieve pain (such as administration of known analgesics, e.g. NSAIDS) would have been self-evident given the guidance of the secondary reference regarding treatment parameters specific to metaxalone (see column 2, lines 43-49, and column 2, lines 23-25, for instance). Furthermore, the determination of workable and/or optimal particle sizes, size distributions and surface areas as claimed would have been reasonably expected to have required the application of no more than routine experimentation on the part of the skilled artisan, consistent with established precedent. See, e.g., See In re Aller, 105 USPQ 233, 235 (CCPA 1955); In re Boesch, 205 USPQ 215 (CCPA 1980); and In re Peterson, 65 USPQ2d 1379 (Fed. Cir. 2003). (Collectively holding that it is generally

prima facie obvious to determine workable or optimal values within a prior art disclosure through the application of routine experimentation).

Provisional Nonstatutory ("Obviousness-Type") Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-18, 23 and 27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of USSN 10/502,896 in view of Liversidge et al (USP 5,145,684).

This is a provisional rejection because the conflicting claims have not yet been patented.

The conflicting claims recite metaxalone compositions having increased bioavailability (as reflected by the increase in initial plasma levels), which are formulated in rapid release compositions. The secondary reference teaches increasing the bioavailability of hydrophobic

drugs by formulating them as surface-modified nanoparticles (as previously discussed supra), and further teaches that the final pharmaceutical formulation may be tailored to meet the requirements of various administrative parameters, including duration of treatment. See the passage bridging column 7, line 53 to column 8, line 9. Accordingly, where high initial plasma levels were desired, it would have been obvious to have formulated the instant compositions in rapid release form (using appropriate excipients for this purpose such as superdistintegrants) in accordance with this teaching.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached at (571) 272-0580 on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614